Celcuity Presents Updated Results from Phase 1b Study of Gedatolisib in Treatment-Naïve Patients at the 2023 ESMO Breast Cancer Annual Congress

May 12, 2023

Median progression free survival (PFS) was 48.6 months in treatment-naïve patients with HR+/HER2- advanced breast cancer who were treated with gedatolisib in combination with palbociclib and letrozole

Median duration of response (DOR) was 46.9 months

MINNEAPOLIS, MN / ACCESSWIRE / May 12, 2023 / Celcuity Inc. (NASDAQ:CELC), a clinical-stage biotechnology company focused on development of targeted therapies for oncology, today announced that updated results from a Phase 1b trial evaluating gedatolisib, a pan-PI3K/mTOR inhibitor, in combination with palbociclib, a CDK4/6 inhibitor, and letrozole, an aromatase inhibitor, were presented at the 2023 European Society for Medical Oncology (ESMO) Breast Cancer Annual Congress in Berlin, Germany.

The presentation reported efficacy and safety data in treatment-naïve patients with HR+, HER2- advanced breast cancer enrolled in Escalation Arm A and Expansion Arm A. Median progression-free survival (mPFS) and median duration of response (mDOR) data was updated as of March 16, 2023. For treatment-naïve patients in Escalation Arm A (n=11) and Expansion Arm A (n=30), median PFS was 45.8 months and 48.6 months, respectively. When treatment-naïve patients from both arms were combined (n=41), mPFS was 48.6 months and mDOR was 46.9 months. Median PFS in Expansion Arm A had not yet been reached when this data was reported at the San Antonio Breast Cancer Symposium last December.

"The median PFS and DOR results reported for gedatolisib in combination with letrozole and palbociclib are very encouraging and compare favorably to published data for current front-line standard-of-care treatments for patients with HR+, HER2- advanced breast cancer," said Igor Gorbatchevsky, MD, Chief Medical Officer of Celcuity. "The results warrant further evaluation of gedatolisib in combination with a CDK4/6 inhibitor and endocrine therapy in early line settings, including first-line, neoadjuvant, or adjuvant indications."

Phase 1b Study Design and Results for Treatment-Naïve Patients

The company's Phase 1b clinical trial enrolled patients with HR+, HER2- advanced breast cancer and treated them with gedatolisib in combination with palbociclib and an endocrine therapy (either fulvestrant or letrozole). The study enrolled a total of 138 patients in two dose escalation and four dose expansion arms. Updated efficacy and safety data from treatment naïve patients from Escalation Arm A and Expansion Arm A was presented at the ESMO Breast Cancer Congress (see Table 1).

Table 1: B2151009 Efficacy Summary - Treatment-Naïve Population

	Escalation Arm A	**Expansion Arm A**	**Total Treatment-Naïve**
Responses (Evaluable and Measurable Disease)[1], N (%)	**N=7**	**N=26**	**N=33**
CR	0	1 (3.8)	1 (3.0)
PR	4 (57.1)	21 (80.8)	25 (75.8)
SD	3 (42.9)	3 (11.5)	6 (18.2)
Unconfirmed PR	0	0	0
Durable SD (≥ 24	1 (14.3)	2 (7.7)	3 (9.1)

weeks)			
PD	0	1 (3.8)	1 (3.0)
ORR[1]	4 (57.1)	22 (84.6)	26 (78.8)
Median DOR, mos (95% CI)[2]	39.7 (30.5, NR)	46.9 (11.3, NR)	46.9 (24.6, 49.5)
Progression-Free Survival (Full Analysis Set)	**N=11**	**N=30**	**N=41**
Median PFS, mos (95% CI)	45.8 (32.3, NR)	48.6 (11.6, NR)	48.6 (30.4, NR)

The two arms were not randomized. (1) Subjects with measurable disease in response evaluable analysis set per RECIST v1.1; (2) Confirmed responders in the full analysis set; CR, complete response; DOR, duration of response; mos, months; NR, not reached; ORR, objective response rate; PD, progressive disease; PFS, progression free survival; PR, partial response; SD, stable disease.

About Gedatolisib

Gedatolisib is an investigational, pan-PI3K and mTOR inhibitor with low nanomolar potency for all Class I PI3K isoforms and mTORC1 and mTORC2. Its mechanism of action and pharmacokinetic properties are highly differentiated from other therapies that target PI3K or mTOR alone or together. Inhibiting all four Class I PI3K isoforms and mTOR limits the potential development of drug resistance compared to isoform-specific PI3K or mTOR specific inhibitors. A robust response rate and a manageable side effect profile were reported for a Phase 1b clinical trial that evaluated gedatolisib in combination with palbociclib and endocrine therapy in patients with HR+/HER2- advanced breast cancer. A Phase 3 clinical trial, VIKTORIA-1, evaluating gedatolisib in combination with fulvestrant with or without palbociclib in patients with HR+/HER2- advanced breast cancer is currently enrolling patients.

About Celcuity

Celcuity is a clinical-stage biotechnology company focused on development of targeted therapies for treatment of multiple solid tumor indications. The company's lead therapeutic candidate is gedatolisib, a potent, pan-PI3K and mTOR inhibitor. Its mechanism of action and pharmacokinetic properties are highly differentiated from other currently approved and investigational therapies that target PI3K or mTOR alone or together. A Phase 3 clinical trial, VIKTORIA-1, evaluating gedatolisib in combination with fulvestrant with or without palbociclib in patients with HR+/HER2- advanced breast cancer is currently enrolling patients. More detailed information about the VIKTORIA-1 study can be found at ClinicalTrials.gov. The company's CELsignia companion diagnostic platform is uniquely able to analyze live patient tumor cells to identify new groups of cancer patients likely to benefit from already approved targeted therapies. Celcuity is headquartered in Minneapolis. Further information about Celcuity can be found at Celcuity.com. Follow us on LinkedIn and Twitter.

Forward-Looking Statements

This press release contains statements that constitute "forward-looking statements" including, but not limited to, the timing of initiating and enrolling patients in, and receiving results from, clinical trials, such as Celcuity's Phase 3 VIKTORIA-1 clinical trial, the costs and expected results from any ongoing or planned clinical trials, the impact on gedatolisib and Celcuity of preliminary clinical trial results, any potential benefits resulting from Breakthrough Therapy designation for gedatolisib, and other expectations with respect to Celcuity's lead product candidate, gedatolisib and its CELsignia platform. In some cases, you can identify forward-looking statements by terminology such as "may," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "intends" or "continue," and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. Forward-looking statements are subject to numerous risks, uncertainties, and conditions, many of which are beyond the control of Celcuity. These include, but are not limited to, those risks set forth in the Risk Factors section in Celcuity's Annual Report on Form 10-K for the year ended December 31, 2022 filed with the Securities and Exchange Commission on March 23, 2023. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Celcuity undertakes no obligation to update these statements for revisions or changes after the date of this press release, except as required by law.

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